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SUBJECT: SPECIAL 301: SLOVAKIA PROCURES NEW STORAGE FACILITY

REF: A) BRATISLAVA 143 B) December 15, 2005 DVC between USG

and GOS representatives.

¶1. Summary - The Ministry of Health (MOH) has found a secure building for the storage of proprietary drug application data on a military base. Econ officers visited the facility on March 8 and were fully satisfied that once it is renovated according to MOH's plans the building will serve as a secure and functional structure for the storage of sensitive pharmaceutical data. Together with the recent successful efforts to enhance linkage regulations to better protect patent holders, this development gives us confidence that Slovakia is committed to fully resolving our outstanding 301 concerns. We strongly recommend removing Slovakia from the 2006 Watch List, believing that failure to do so would be counterproductive and could harm future efforts to work with the Ministries of Health and Economy in areas of mutual concern. End summary.

NEW STORAGE FACILITY

¶2. As outlined in reftel A, the MOH received three bids for a public tender for a secure storage facility and had planned to select a winning bid by the end of February. Before this process was complete, however, Minister of Health Rudolf Zajac notified the Embassy that his ministry had identified a vacant government building that fit the criteria and could be procured more quickly and at a fraction of the cost of a private facility. The building belongs to the Ministry of Defense and is located on a military base in Malacky, about 45 minutes north of Bratislava. It is a former mess hall and officers club that has not been used for several years. The Ministry of Defense has agreed to transfer this building to the MOH.

¶3. Econoffs visited the facility on March 8 with officials from the Drug Control Authority (SUKL), who together with the MOH will be responsible for the renovation and transfer of documents to the Malacky facility. The 20 year-old two-story building is in good condition and will provide sufficient space (approximately 13,750 square feet) to house the sensitive drug company files. The SUKL officials brought detailed architectural designs and used the visit to provide an overview of their renovation plans. SUKL plans to tear down the interior walls to make one large warehouse-like room on each level, redo the floors, and install an elevator. They will also install security and fire alarm systems, and reduce the number of exterior entrances to the building. Security will also be enhanced by the fact that the building is located on an active military base and will have round-the-clock military security. SUKL estimates that

the total cost of reconstruction will be approximately USD 500,000. As outlined in Ref. A, the MOH has already allocated funds to SUKL for this project.

¶4. SUKL requested the Embassy's informal approval of the facilities before finalizing arrangements for the transfer of title from the Ministry of Defense and moving ahead with reconstruction. (Note: Ambassador sent a letter to Minister of Health Zajac on March 9 noting our satisfaction with the facilities and encouraging the minister to move as quickly as possible to finalize arrangements and begin construction.) By their own estimates, SUKL will need two to four weeks to transfer the title and get the necessary building permits. After selecting a contractor, construction is expected to take two months. SUKL plans to finish the renovations and move the proprietary data to the Malacky facility by July or August, 2006.

LINKAGE LEGISLATION SENT TO PARLIAMENT

¶5. The draft amendment to the Medicines Act was approved by the cabinet without changes on February 15 and is the second item that will be taken up by the Parliament when the new session opens on March 15. The legislation obligates SUKL to notify the patent holder when it receives a request for marketing approval from a generic company, and to coordinate with the Patent Office if there is any question as to the status of the patent. As outlined in Ref A, as an interim measure the MOH issued a decree in January requiring SUKL to abide by the provisions of the draft amendment until it becomes law. A translated version of the draft amendment and the MOH decree will be sent by email to Washington officials.

¶6. Comment - After our visit to Malacky and briefing by SUKL officials, we are fully satisfied that once the building is renovated it will meet all of the criteria for a secure storage facility for proprietary drug application data. Although the new facilities will not be ready by March 31, as promised by SUKL officials at the Ref B. digital video conference (DVC), the Health Minister and other GOS officials have taken major steps towards this goal and have given every indication that they are committed to completing the process as soon as possible. Even the Director of SUKL, Milan Rybar, who has been a reluctant participant from the beginning of our discussions with the GOS, now seems enthusiastic about the project and even requested our help in encouraging the MOH to act quickly to obtain the necessary permits so that they can begin work on the building.

¶7. Comment continued - GOS officials have acted in good faith to meet the commitments that they made at the December 15, 2005 DVC to address the outstanding IPR concerns that have kept them on the Watch List for the last five years. Although some work implementing these strong commitments remains to be done, we strongly recommend acknowledging their efforts by removing Slovakia from the 2006 Watch List. Leaving Slovakia on the list would be counterproductive, souring the strong working relationship that we have built with the ministries of health and economy and making further cooperation to improve the business environment more difficult. End Comment.

VALLEE